

U.S. Patent Publication US-2015-0182843-A1; and PCT Patent Publication WO 2015/175838 A1.

**[0009]** In general, pressure sensor(s) described herein may be associated with any type of substrate that contacts the body, directly or indirectly. Thus, pressure sensor(s) and sensor systems described herein, including e-textile pressure sensors and a variety of other types of sensors, with suitable leads and conductive traces, may be associated with a variety of substrates including, without limitation, garments intended to be worn (directly or indirectly) against the skin of an individual, such as a shirt or tunic, underwear, leggings, socks, footies, gloves, caps, bands such as wrist bands, leg bands, torso and back bands, brassieres, and the like. Pressure sensors and sensor systems may additionally be associated with bands and/or wraps having different sizes and configurations for fitting against or wrapping around a portion of an individual's body, and with compression garments, bandages, wound dressing materials, as well as with other types of accessories that contact a user's body surface (directly or indirectly) such as insoles, shoes, boots, belts, straps, and the like.

**[0010]** The pressure sensor(s) and sensor systems described herein provide objective data relating to pressure and/or force or and/shear (or measurements or values that are derivative thereof) at identifiable spatial locations on or near a body surface where the sensor(s) are positioned. Signals collected at pressure sensor sites are conveyed to a host data processing system for data processing and analysis, optionally through one or more electronic intermediates, and user-specific data, analytics, recommendations, and the like, may be communicated directly to the user, or to an intermediate for analysis, review, and/or communication to the user. The sensor(s) and sensor systems may therefore be used to evaluate how well a shoe, prosthetic, compression garment, other type of garment or the like conforms to a user's body and to provide detection and relative and/or quantitative measurements of pressure, force and/or shear at identifiable spatial locations while the user is at rest and during various activities, substantially in real time. The sensor(s) and sensor systems may also be used to detect and monitor various aspects of a user's gait, substantially in real time.

**[0011]** Pressure sensors employed with flexible substrates are preferably flexible and substantially conform to a body surface, and are capable of sensing force and/or pressure and/or shear exerted on the sensor, and thereby on the underlying body surface. Each sensor is electrically connected (directly or indirectly) to a flexible conductive trace associated with the substrate. Conductive traces terminate at conductive signal transfer terminals, which may be associated with the substrate or with a sensor assembly. One or more of the sensor(s) and conductive traces may be stretchable and/or elastic as well as being flexible.

**[0012]** In some embodiments, the pressure sensor(s) may comprise flexible resistive and/or conductive materials such as resistive or conductive textile materials. Suitable flexible resistive fabric materials are available, for example, from VTT/Shieldex Trading USA, 4502 Rt-31, Palmyra, N.Y. 14522, from Statex Productions & Vertriebs GmbH, Kleiner Ort 11 28357 Bremen Germany, and from Eeonix Corp., 750 Belmont Way, Pinole, Calif. 94564. Sensors comprising e-textile materials may be associated with a substrate or carrier layer, or they may be woven into or integrated in the material of the substrate. In some embodiments, the pressure

sensor(s) may comprise other types of flexible conductive or resistive materials, such as resistive or conductive thermoplastic elastomers (TPEs), resistive or conductive inks, resistive or conductive silicon-containing materials, or other flexible resistive or conductive materials that may be applied directly to a substrate, or that may be applied to a carrier layer, forming a sensor assembly that may be bonded or adhered to a substrate.

**[0013]** In some embodiments, the conductive traces may comprise flexible electrically conductive materials, such as conductive textile materials, conductive threads, yarns, or the like that may be associated with a substrate or carrier layer or woven into or integrated in the material of the substrate. In some embodiments, the conductive traces may comprise other types of flexible conductive materials, such as thermoplastic elastomers (TPEs), conductive inks, conductive silicon-containing materials or other flexible conductive materials that may be applied directly to a substrate, or that may be applied to a carrier layer, forming a sensor assembly that may be bonded or adhered to a substrate. Garments and accessories incorporating such sensor systems and sensor assemblies may be comfortably worn by users in many conditions, providing real time monitoring of conditions at or near body surfaces.

**[0014]** The signal transfer terminal(s) associated with the substrate may be matingly received in signal receipt terminals associated with a Dedicated Electronic Device (DED) that is attachable to the substrate and serves as a (temporary or permanent) data collection device. The DED may also (optionally) house batteries or other energy storage devices and serve as a sensor-charging device. The DED may communicate with one or more external electronic device(s), such as a smartphone, personal computing device/display, host computer, or the like for signal transfer, processing, analysis and display to a user and/or others. In some embodiments, the external electronic device, and/or the DED, communicates with an external, hosted computing system (operated, e.g., at a centralized, hosted facility and/or in the "Cloud") that provides additional data analysis, formulates feedback, notifications, alerts, and the like, that may be displayed to the user, a caretaker, and/or a clinician through one or more computing and/or display devices.

**[0015]** In some embodiments, one or more piezoresistive sensor(s) detects changes in voltage or resistance across a sensor surface area that is associated with force exerted on the sensor, which is related to pressure (as force per unit surface area) and/or shear. In some embodiments, FSR (Force Sensitive Resistor) and/or piezo-resistive sensors may be used. One type of piezoresistive force sensor that has been used previously in footwear pressure sensing applications, known as the FLEXIFORCE® sensor, can be made in a variety of shapes and sizes, and measures resistance, which is inversely proportional to applied force. These sensors use pressure sensitive inks with conductive leads terminating in pins, with the pressure sensitive area and leads sandwiched between thin, flexible film layers. FLEXIFORCE® sensors are available, for example, from Tekscan, Inc., 307 West First Street, South Boston, Mass. 02127-1309 USA. Other types of sensors may also be integrated in or associated with various substrate or carrier materials (e.g., garments, sheet materials and the like), including sensors providing data relating to temperature, moisture, humidity, stress, strain, heart rate, respiratory rate, blood pressure, blood oxygen saturation, blood flow, local gas content, bacterial content,